IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re United States Patent Application of:		**Docket No.:**	**014811-673.119 US**
Applicant(s):	**Ekwuribe, et al.**	**Examiner:**	**Phyllis G. Spivack**
Application No.:	**10/594,046**	**Art Unit:**	**1614**
Filing Date:	**September 25, 2006**	**Confirmation No:**	**8968**
Title:	**METHODS AND COMPOSITIONS EMPLOYING 4-AMINOPHENYLACETIC ACID COMPOUNDS**	**Customer No.**	**24239**

RESPONSE TO AUGUST 7, 2008 OFFICE ACTION IN U.S. PATENT APPLICATION NO. 10/594,046

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the August 7, 2008 Office Action, please amend the application as follows:

In the Claims

1. (Original) A pharmaceutical composition comprising two or more therapeutic agents selected from the group consisting of:

(a) azo-bonded 4-APAA compound;

(b) non-azo bonded 4-APAA compound;

(c) azo-bonded 5-ASA compound;

(d) non-azo bonded 5-ASA compound;

(e) 4-APAA compound azo bonded to a 5-ASA compound.

2. (Currently amended) The pharmaceutical composition of claim 1 further comprising a third therapeutic agent selected from the group consisting of: steroids, antibiotics, stool softeners, stool hardeners, nutraceuticals, probiotic agents and organisms, and nicotinic agents.

3. (Original) The pharmaceutical composition of claim 1 formulated to deliver the therapeutic agents to the small intestine and/or the colon.

4. (Original) The pharmaceutical composition of claim 1 formulated to release the therapeutic agents along the length of the small intestine and the colon.

5. (Original) The pharmaceutical composition of claim 1 formulated to release the therapeutic agents along the length of the distal portion of the small intestine and the colon.

6. (Original) The pharmaceutical composition of claim 1 formulated to release the therapeutic agents along the length of the colon.

7. (Original) The pharmaceutical composition of claim 1 formulated to pass through the stomach and to release the active agent in the intestine.

8. (Original) The pharmaceutical composition of claim 1 formulated as a suppository.

9. (Original) The pharmaceutical composition of claim 1 formulated for administration as an enema.

10. (Original) The pharmaceutical composition of claim 1 formulated as a mouth wash.

11. (Original) The pharmaceutical composition of claim 1 formulated for vaginal administration.

12. (Original) The pharmaceutical composition of claim 1 formulated for intra-uterine administration.

13. (Original) The pharmaceutical composition of claim 1 formulated for topical administration.

14. (Original) The pharmaceutical composition of claim 1 formulated for administration to the eye.

15. (Original) The pharmaceutical composition of claim 1 formulated to release:

(a) at least one component selected from:

(i) a first component comprising one or more of the therapeutic agents formulated for release in the stomach,

(ii) a second component comprising one or more of the therapeutic agents formulated for release in the small intestine or distal portion of the small intestine, and

(b) a third component comprising one or more of the therapeutic agents formulated for release in the colon.

16. (Currently amended) The pharmaceutical composition of claim ~~θ~~ 15 wherein:

(a) the first component comprises a 5-ASA compound;

(b) the second component comprises a 5-ASA compound and a 4-APAA compound formulated for release in a distal portion of the small intestine;

(c) the third component comprises a 5-ASA compound and a 4-APAA compound.

17. (Currently amended) The pharmaceutical composition of claim ~~θ~~ 15 wherein:

(a) the first component comprises a 5-ASA compound;

(b) the second component comprises:

(i) a 5-ASA compound formulated for release in the small intestine;

(ii) a 5-ASA compound and a 4-APAA compound formulated for release in a distal portion of the small intestine;

(c) the third component comprises a 5-ASA compound and a 4-APAA compound.

18. (Currently amended) The pharmaceutical composition of claim ~~θ~~ 15 wherein:

(a) the first component comprises a 5-ASA compound;

(b) the second component is not present;

(c) the third component comprises a 5-ASA compound and a 4-APAA compound.

19. (Currently amended) The pharmaceutical composition of claim ~~θ~~ 15 wherein:

(a) the first component comprises a 5-ASA compound;

(b) the second component comprises a 5-ASA compound formulated for release in the small intestine;

(c) the third component comprises a 5-ASA compound and a 4-APAA compound.

20. (Currently amended) The pharmaceutical composition of claim ~~θ~~ 15 wherein:

(a) the first component comprises a 4-APAA compound;

(b) the second component comprises a 5-ASA compound and a 4-APAA compound formulated for release in a distal portion of the small intestine;

(c) the third component comprises a 5-ASA compound and a 4-APAA compound.

21. (Currently amended) The pharmaceutical composition of claim ~~θ~~ 15 wherein:

(a) the first component comprises a 4-APAA compound;

(b) the second component comprises:

(i) a 4-APAA compound formulated for release in the small intestine; and

(ii) a 5-ASA compound and 4-APAA compound formulated for release in a distal portion of the small intestine;

(c) the third component comprises a 5-ASA compound and a 4-APAA compound.

22. (Currently amended) The pharmaceutical composition of claim ~~θ~~ 15 wherein:

(a) the first component comprises a 4-APAA compound;

(b) the second component is not present;

(c) the third component comprises a 5-ASA compound and a 4-APAA compound.

23. (Currently amended) The pharmaceutical composition of claim ~~θ~~ 15 wherein:

(a) the first component comprises a 4-APAA compound;

(b) the second component comprises a 4-APAA compound formulated for release in the small intestine;

(c) the third component comprises a 5-ASA compound and a 4-APAA compound.

24. (Currently amended) The pharmaceutical composition of claim ~~θ~~ 15 wherein:

(a) the first component is not present;

(b) the second component comprises a 5-ASA compound and 4-APAA compound formulated for release in a distal portion of the small intestine;

(c) the third component comprises a 5-ASA compound and a 4-APAA compound.

25. (Currently amended) The pharmaceutical composition of claim ~~θ~~ 15 wherein:

(a) the first component is not present;

(b) the second component comprises:

(i) a 5-ASA compound formulated for release in the small intestine;

(ii) a 5-ASA compound and 4-APAA compound formulated for release in a distal portion of the small intestine;

(c) the third component comprises a 5-ASA compound and a 4-APAA compound.

26. (Currently amended) The pharmaceutical composition of claim ~~θ~~ 15 wherein:

(a) the first component is not present;

(b) the second component comprises a 5-ASA compound formulated for release in the small intestine;

(c) the third component comprises a 5-ASA compound and a 4-APAA compound.

27. (Currently amended) The pharmaceutical composition of claim ~~θ~~ 15 wherein:

(a) the first component is not present;

(b) the second component comprises a 5-ASA compound and 4-APAA compound formulated for release in a distal portion of the small intestine;

(c) the third component comprises a 5-ASA compound and a 4-APAA compound.

28. (Currently amended) The pharmaceutical composition of claim ~~θ~~ 15 wherein:

(a) the first component is not present;

(b) the second component comprises:

(i) a 4-APAA compound formulated for release in the small intestine; and

(b) a 5-ASA compound and 4-APAA compound formulated for release in a distal portion of the small intestine;

(c) the third component comprises a 5-ASA compound and a 4-APAA compound.

29. (Currently amended) The pharmaceutical composition of claim ~~8~~ 15 wherein:

(a) the first component is not present;

(b) the second component comprises a 4-APAA compound formulated for release in the small intestine;

(c) the third component comprises a 5-ASA compound and a 4-APAA compound.

30. (Currently amended) A method of treating an inflammatory ~~gastro~~intestinal condition comprising administering to a subject a pharmaceutical composition of claim 1,2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18, 19, 20, 21, 22, 23, 24, 25, 26, 27, 28 or 29 in an amount sufficient to reduce the inflammatory gastrointestinal condition.

31. (Cancelled).

REMARKS

Objection to Claims

Applicants have amended claims 2 and 30 to overcome the indefinite objections thereby obviating this objection.

Information Disclosure Statement

Applicants have included herewith a replacement sheet providing the publication date. The molecule discussed in the Beilstein search, was originally published in 1884. The IDS form now states this date and is located in Appenidix A.

Previously Filed Terminal Disclaimers

Applicants filed three Terminal Disclaimers on September 7, 2007 and a copy of each is included. The fees have already been paid for these documents. The Terminal Disclaimers include one for US Patent Nos. 7,119,119, 6,903,082 and 6,583,128.

Fees Due

Applicants believe that no fee is due for entry of this amendment, however, in the event an additional fee is found due, the U.S. Patent and Trademark Office is hereby authorized to charge any additional amount necessary to the entry of this amendment to Deposit Account No. 13-4365 of Moore & Van Allen PLLC.

Conclusion

Applicants have satisfied the requirements for patentability. All pending claims are free of the art and fully comply with the requirements of 35 U.S.C. §112. It therefore is requested that Examiner Spivack reconsider the patentability of pending claims in light of the distinguishing remarks herein and withdraw all rejections, thereby placing the application in condition for allowance. Notice of the same is earnestly

solicited. In the event that any issues remain, Examiner Spivack is requested to contact the undersigned attorney at (919) 286-8089 to resolve same.

Respectfully submitted,

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APPENDIX A

PTO/SB/08b (08-05)
Approved for use through 06/30/2006. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 10 of 10

Complete if Known	
Application Number	10/594,046
Filing Date	September 25, 2006
First Named Inventor	Nnochiri N. Ekwuribe
Art Unit	1614
Examiner Name	Phyllis G. Spivack
Attorney Docket Number	014811.673.119

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No.[1]	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T[2]
	241	M.C. Di PAOLO et al.; Sulphasalazine and 5-aminosalicylic acid in long-term treatment of ulcerative colitis: report on tolerance and side-effects, Digest Liver Dis.; 2001; pp. 583-589; 33	
	242	E. K. FIELDS et al.; Diaryl Substituted Maleic Anhydrides; J. Org. Chem.; 1999; pp. 5185-5170; 55; American Chemical Society	
	243	FRIEDRICH NERDEL et al.; Chemical Abstracts; 1961; pp. 443-444; Vol. 55	
	244	Beilstein Search Results, 5523653, 1884.	
	245	FRANK D. KING, Bioisosteres, Conformational Restriction, and Pro-drugs – Case History: An Example of a Conformational Restriction Approach. Medicinal Chemistry : Principles and Practice; 1994; pp. 208-225 (pp. 216-217, Table 4); Cambridge, RSC, GB	

Examiner Signature		Date Considered	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

[1] Applicant's unique citation designation number (optional). [2] Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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